IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

JAN VALLEJO, individually and as personal representative of the estate of Steve Vallejo,

Plaintiffs,

vs.

AMGEN, INC., et al.,

Defendants.

8:14-CV-50

MEMORANDUM AND ORDER

The plaintiff, Jan Vallejo, is suing the defendants in her personal capacity and as the personal representative of the estate of her deceased husband, Steve Vallejo ("decedent"). The defendants, Amgen, Inc., Pfizer, Inc., and Wyeth, Inc., (collectively "Amgen") have moved for summary judgment. For the reasons explained below, Amgen's motion will be granted.

BACKGROUND

Amgen manufactures, designs, distributes, sells, and supplies Enbrel, a prescription drug commonly used to treat, among other conditions, moderate to severe plaque psoriasis. The decedent suffered from psoriasis, and in 2004, he was prescribed Enbrel. Filing 142 at 2; filing 27 at 5. Vallejo alleges that, while on Enbrel, the decedent developed complications from myelodysplastic syndrome ("MDS")—a disorder that can transform into leukemia or otherwise lead to severe bone marrow failure. Filing 142 at 3. The decedent died on May 21, 2011. Filing 27 at 5.

Vallejo claims that the decedent's use of Enbrel is the direct and proximate cause of the injuries resulting in his death. Filing 27 at 5. Specifically, she alleges that Amgen failed to warn the decedent or his physicians that Enbrel could cause MDS, and that Amgen demonstrated "conscious disregard" for the safety of patients in the design and sale of the drug. Filing 27 at 5. Her amended complaint raises claims for strict liability defective design, strict liability failure to warn, breach of express warranty, negligence, wrongful death, and loss of consortium. Filing 27.

STANDARD OF REVIEW

Summary judgment is proper if the movant shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(a). The movant bears the initial responsibility of informing the Court of the basis for the motion, and must identify those portions of the record which the movant believes demonstrate the absence of a genuine issue of material fact. *Torgerson v. City of Rochester*, 643 F.3d 1031, 1042 (8th Cir. 2011) (en banc). If the movant does so, the nonmovant must respond by submitting evidentiary materials that set out specific facts showing that there is a genuine issue for trial. *Id.*

On a motion for summary judgment, facts must be viewed in the light most favorable to the nonmoving party only if there is a genuine dispute as to those facts. *Id.* Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the evidence are jury functions, not those of a judge. *Id.* But the nonmovant must do more than simply show that there is some metaphysical doubt as to the material facts. *Id.* In order to show that disputed facts are material, the party opposing summary judgment must cite to the relevant substantive law in identifying facts that might affect the outcome of the suit. *Quinn v. St. Louis County*, 653 F.3d 745, 751 (8th Cir. 2011). The mere existence of a scintilla of evidence in support of the nonmovant's position will be insufficient; there must be evidence on which the jury could conceivably find for the nonmovant. *Barber v. C1 Truck Driver Training, LLC*, 656 F.3d 782, 791-92 (8th Cir. 2011). Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial. *Torgerson*, 643 F.3d at 1042. A complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

DISCUSSION

The underlying dispute concerns causation: that is, whether Vallejo has adduced sufficient evidence to demonstrate a causal relationship between Enbrel and MDS. Amgen argues that no such evidence exists, citing Vallejo's failure to procure expert testimony regarding Enbrel's connection, if any, to the purported medical condition. Filing 142 at 2. It further suggests that, because expert testimony "is required to establish medical causation," there is an absence of proof concerning an essential element of Vallejo's claims. Filing 154 at 6. Vallejo disagrees, arguing that she need not present expert testimony. To support this contention, Vallejo points to a 2016 medical report in which Amgen allegedly concedes the causal relationship at issue. Filing 149 at 14. Thus, because Amgen purportedly "admits" causation, Vallejo

asserts that "[a] skilled or professional expert does not need to testify[.]" Filing 149 at 14.

Before turning to the merits of these arguments, it is worth noting the complicated and contentious procedural history of this case—particularly as it pertains to the issue of medical causation. This history includes, at least for present purposes, several discovery-related orders from the magistrate judge dating back to May 2015. At that time, the magistrate issued a bifurcated (or phased) discovery plan, with the first phase limited to "general medical causation; that is, whether using Enbrel can cause MDS."[1] Filing 55 at 5; filing 63 at 1. In doing so, the magistrate recognized that "[Vallejo] cannot prevail on [her] claims of failure to warn absent prima facie evidence which casually links ingestion of Enbrel to Steve Vallejo's illness and death." Filing 55 at 4. Over the next several months, the magistrate judge ordered Amgen to turn over certain "adverse event reports" and "Enbrel studies," and to produce for deposition Dr. Jan Iles, Amgen's global safety officer in charge of Enbrel. *See* filing 83 at 12-13. Amgen complied.

On August 10, 2016, the magistrate judge asked Vallejo's counsel whether—in light of deposition testimony and medical disclosures—he had secured an expert witness. Filing 119 at 65. Counsel said yes. So, the following day, the magistrate ordered Vallejo to disclose all retained and non-retained experts "expected to testify at trial on behalf of the Plaintiff . . . on the issue of whether ingesting Enbrel can cause MDS." Filing 115 at 4. Vallejo responded, filing a "designation of experts for general causation." Filing 121-1 at 2. There, Vallejo lists as her sole expert witness "John Doe (Pfizer Employee)." Filing 121-1 at 2. This individual, Vallejo claims, "is expected to testify on general causation as to whether Enbrel causes or contributes to the development of MDS in humans." Filing 121-1 at 2.

Following this disclosure, and at the conclusion of the first phase of discovery, Amgen moved for summary judgment.

CAUSATION

Causation is, as both parties acknowledge, an essential element of Vallejo's claims. Filing 149 at 13-14; filing 142 at 9-14; *see*, *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 988 (8th Cir. 2001); *Grant v. Pharmative*, LLC, 452 F. Supp. 2d 903, 907 (D. Neb. 2006); *Roskop Dairy, LLC v. GEA Farm Tech., Inc.*, 871 N.W.2d 776, 794 (Neb. 2015). Ordinarily, in cases involving complex technical, medical, or scientific issues, causation

[1] To be clear: Vallejo must prove both general *and* specific causation. *See Grant v. Pharmative, LLC*, 452 F. Supp. 2d 903, 909 (D. Neb. 2006). But pursuant to the magistrate judge's order, the first phase of discovery was limited to general causation only. *See* filing 63 at 2.

must be established by expert testimony. *See*, *Nuzum v. Chlorella*, 2006 WL 3825111, at *3 (D. Neb. 2006); *Thone v. Reg. W. Med. Ctr.*, 745 N.W.2d 898, 908 (Neb. 2008); *Hohnstein v. W.C Frank*, 468 N.W.2d 597, 602 (Neb. 1991). The absence of expert testimony on the question of causation may "result[] in an insufficiency of proof" or otherwise warrant summary judgment. *Nuzum*, 2006 WL 3825111 at *3; *see also*, C.*W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 838 (7th Cir. 2015); *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1203 (11th Cir. 2010); *In re Mirena IUD Products Liability Litigation*, 202 F. Supp. 3d 304, 312 (S.D.N.Y. 2016).

These principles—and in particular, the requirement of expert testimony—pervade the 3-year pendency of this case. Indeed, throughout the first phase of discovery, the magistrate judge *repeatedly* cautioned Vallejo that she would need to produce expert testimony to establish a causal link between Enbrel and MDS. The magistrate judge's message was, and has always been, clear:

> By alleging this causal connection in his complaint, the plaintiff and his counsel are certifying that they have investigated the facts in good faith and there is evidence supporting all elements of Plaintiff's claim, including medical causation. A mere hypothesis that causation exists, as distinguished from reliable scientific evidence, is not sufficient. . . . [Therefore, i]f the plaintiffs cannot produce reliable expert testimony to support a causal connection between Enbrel and MDS, *the defendants will be entitled to summary judgment at the outset of the case*.

Filing 63 at 1-2 (emphasis added) (citing *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950 (D. Minn. 2009)).

Despite the Court's admonishments, and despite being permitted to engage in directed discovery on matters of causation, Vallejo has *still* failed to disclose admissible expert testimony on the complex issue of medical causation. Rather, Vallejo takes the position that, given the evidence adduced, she need not present such testimony. To this end, she contends (without any support in the law) that an opposing party's purported "admission" regarding causation obviates or excuses the requirement for scientific evidence. And these "admissions," she says, are in the form of a 2016 MedWatch report in which an unnamed, unidentified Pfizer employee wrote: "Based on the information provided; drug profile, temporal association and positive dechallenge result, the events myelodysplastic syndrome and pancytopenia are considered related to the use of etanercept." Filing 149 at 8; filing 152 at 4. According to Vallejo, this statement "establishes" the causal

connection at issue, and "is such that there is no need for an expert witness to support Plaintiff's claims." *See* filing 149 at 14.

She is incorrect. As an initial matter, MedWatch reports are simply a doctor's or medical practitioner's account of a particular patient's reaction to a drug or other stimulus, accompanied by a description of the relevant surrounding circumstances.[2] *Glastetter*, 252 F.3d at 989-90. As such, the Eighth Circuit has certainly questioned their reliability, particularly when cited as evidence of general or specific causation. *See Glastetter*, 252 F.3d at 990. And for good reason: as the circuit court has explained, such reports make little attempt to screen out alternative causes for a patient's condition, frequently lack analysis, and often omit relevant facts about the patient's condition. *Id.* at 989-90. Accordingly, "[c]ausal attribution based on case studies must be regarded with caution." *Id.* at 990 (quoting *Reference Manual on Scientific Evidence* at 475 (Fed. Judicial Ctr. 2000)); *see also Nozinich v. Johnson & Johnson, Inc.*, 2011 WL 13124085, at *8 (W.D. Tenn. 2011) (describing adverse reports as an "uncontrolled collection of perceived adverse reactions") (citing *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005)); *cf., Goldstein v. Centocor*, 2007 WL 7428597, at *3 (S.D. Fla. 2007) ("MedWatch reports are considered 'uncontrolled anecdotal information' which are not reliable sources on which to base opinions as to general or specific causation"); *Ervin v. Johnson & Johnson, Inc.*, 2006 WL 1529582, at *6 (S.D. Ind. 2006).

So, even assuming, *arguendo*, the adverse case report amounts to an "admission" by Amgen, it is difficult to see how—in light of the above principles—it has any bearing on Vallejo's burden of proof. At most, the report suggests a "temporal association" between the pharmaceutical product and the reported medical event of an individual who has no relation to the present dispute. *Glastetter*, 252 F.3d at 990. But that association, if at all, is "not scientifically valid proof of causation." *Id.* And more to the point, there is no support for Vallejo's contention that a single adverse event report based entirely on third party information from unknown sources constitutes a proper substitute for expert testimony.[3] Indeed, as noted above, "[w]hen the

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[2] The present report appears to have been submitted by a Pfizer employee "who received the information from a physician." Filing 152 at 2. The content of the form concerns a 44 year old, adult male patient "who experienced myelodysplastic syndrome . . . while receiving Enbrel." Filing 152 at 2.

[3] And even if it did, the report at issue does not establish that Enbrel *causes* MDS, as Vallejo alleges. Rather, according to the report, "myelodysplastic syndrome and pancytopenia *are considered related to* the use of etanercept." Filing 152 at 4 (emphasis added). Thus, while the notation may suggest an *association* between Enbrel and MDS, it cannot be construed "as an admission of general causation." *Smith v. Pfizer Inc.*, 2001 WL

subject matter is wholly scientific or so far removed from the usual and ordinary experience of the average man that expert knowledge is essential to the formation of an intelligent opinion, *only an expert* can competently give opinion evidence as to the cause of the physical condition." *Hohnstein*, 468 N.W.2d at 602.

Nor is there basis in law or fact for Vallejo's contention that, irrespective of the MedWatch report, she has satisfied her prima facie burden on medical causation by designating as a non-retained expert "John Doe (Pfizer Employee)." *See* filing 149 at 15-16. As Amgen argues, the disclosure is utterly devoid of any information that would allow the Court to assess the qualifications of the expert or the reliability of the proffered testimony. Filing 142 at 11-12; *see Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757 (8th Cir. 2006) (courts must ensure that all scientific testimony is both reliable and relevant). Thus, without more, Vallejo has failed to show by a preponderance of the evidence that the purported testimony is "scientifically valid." *Id.* at 757-58.

And as a final matter, Vallejo has attached as evidence two articles from the *Journal of the American Academy of Dermatology* and a copy of the Canadian Product Monograph[4] for Enbrel. These reports, she suggests, support the contention that Enbrel causes MDS. Filing 149 at 3. But the problem is: they do not. Indeed, in one of the reports, the author writes, "whether etanercept accelerated the evolution of disease, or whether the drug actually caused the disease remains to be determined." Filing 150 at 9. And in the other: "The role etanercept played in the evolution of MDS to AML, if any, is uncertain." Filing 150 at 12. Thus, the only potential *association* between Enbrel and MDS exists in the Canadian Product Monograph, which lists MDS as an "infrequent serious adverse event[]" observed in clinical trials. Filing 150 at 27. But again, the plaintiff must come forward with evidence of *causation*, not (tenuous) *association*.

In any event, for the reasons provided above, the materials do not excuse the need for expert testimony. There is no dispute that Vallejo's allegations involve complex scientific matters, and yet inexplicably—

968369, at *11 (D. Kan. 2001); *King v. Burlington Northern Sante Fe Ry. Co.*, 762 N.W.2d 24, 35 (Neb. 2009) (in the discipline of epidemiology, "an association is not equivalent to causation") (citing *Reference Manual on Scientific Evidence* 336 (2d ed. 2000)).

[4] The Canadian Product Monograph is a "factual, scientific document" which describes a drug's properties, claims, indications and conditions of use. Drug manufacturers in Canada are required to develop a detailed Product Monograph in accordance with certain governmental regulations. *See* Health Canada, "Drugs and Health Products" (July 11, 2014) *available at* http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/monograph/pm_qa_mp_qr-eng.php.

throughout the 3-year life span of this litigation—she has failed to retain an expert.

CONCLUSION

For all of the reasons set forth above, Amgen's motion for summary judgment is granted. *See Celotex*, 477 U.S. at 323.

IT IS ORDERED:

1. Amgen's motion for summary judgment (filing 141) is granted.

2. Vallejo's complaint is dismissed.

3. A separate judgment will be entered.

Dated this 31st day of March, 2017.

BY THE COURT:

John M. Gerrard
United States District Judge